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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
(Pursuant to Section 12, Safe Medical Devices Act of 1990)
EDDY™ Intravascular Infusion Catheter

1. The trade or proprietary name of the device is Medi-tech EDDY™ Intravascular Infusion Catheter. The common or usual name is Continuous Flush Catheter.

2. The EDDY™ Intravascular Infusion Catheter is intended for general Intravascular use, including neuro, peripheral, and coronary vasculature. The catheter is intended to be flow tracked in order to access distal tortuous vasculature. Once the subselective region has been accessed, the catheter can be used for the controlled and selective infusion of diagnostic, embolic, or therapeutic materials into vessels. Diagnostic, embolic, or therapeutic agents to be used in accordance with specifications oulined by the manufacturer.

The device is a single lumen device which facilitates distal vascular access. The catheter is available in two shaft sizes. The larger shaft size models incorporate a 2.7F proximal shaft with a 2.2F flexible distal shaft and a distal internal diameter of .019". The smaller shaft size models incorporate a 2.4F proximal shaft with a 1.7F flexible distal shaft and a distal internal diameter of .013". The catheter is available in usable shaft lengths from 135 to 165cm, in 5cm increments.

The catheter is intended to be flow tracked, but may accommodate steerable hydrophilic guidewires of $\leq$.016" for the larger shaft size models. The EDDY™ is available in straight and bulb tip configurations. Radiopaque markers at the distal tip and the mid-shaft bond facilitate fluoroscopic visualization of the device. The proximal end of the infusion catheter incorporates a standard luer adapter to facilitate the attachment of accessories. The distal end of the catheter is steam shapeable as are other flow tracked catheters currently on the market. A white ink proximal mark is located 100cm from the tip of the catheter to indicate when the stylet is to be removed during insertion of the infusion catheter into the guide catheter.

The outer surface of the EDDY™ catheter is coated with a hydrophilic coating system, except for the proximal 30cm of shaft. The device will be provided sterile, and is intended for one procedure use only (disposable).

Testing and evaluation included shaft burst pressure, tensile, infusion rate, tip flexibility, torque testing, coating durability and lubricity, and *in vivo* studies. Testing was performed to assess the biocompatibility of the device's blood contact materials.

3. Test results verified that the Medi-Tech EDDY™ Intravascular Infusion Catheter meets all of the minimum requirements and is deemed adequate for its intended use. The Medi-Tech EDDY Intravascular Infusion Catheter is considered to be "substantially equivalent" to the ZEPHYR® Infusion Catheter currently marketed by Target Therapeutics, Inc., the Balt MAGIC™ Infusion Catheter marketed by Target Therapeutics, Inc., and the Venture II Intravascular Infusion Catheter currently marketed by Medi-Tech.